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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/594,449

09/26/2006

Takashi Okuda

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EXAMINER

KINSEY WHITE, NICOLE ERIN

ART UNIT

PAPER NUMBER

1648

MAIL DATE

DELIVERY MODE

08/19/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/594,449	Applicant(s) OKUDA ET AL.	
	Examiner NICOLE KINSEY WHITE	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/8/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Withdrawn Rejections

The rejection of claims 1-12 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been withdrawn in view of applicants' amendments to the claims.

The rejection of claims 1 and 4-10 under 35 U.S.C. 102(b) as being anticipated by Keeler et al (U.S. Patent No. 5,443,831) has been withdrawn in view of applicants' amendments to the claims.

The rejection of claims 1 and 4-10 under 35 U.S.C. 102(b) as being anticipated by Audonnet et al (U.S. Patent No. 5,980,906) has been withdrawn in view of applicants' amendments to the claims.

The rejection of claims 1 and 4-10 under 35 U.S.C. 102(b) as being anticipated by Cochran et al (U.S. Patent No. 6,183,753) has been withdrawn in view of applicants' amendments to the claims.

The rejection of claims 1 and 4-10 under 35 U.S.C. 102(b) as being anticipated by Cochran et al (WO 93/25665) has been withdrawn in view of applicants' amendments to the claims.

The rejection of claims 1 and 4-10 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10, 13 and 24 of U.S. Patent No. 6,632,664 (the '664 patent) in view of Tong et al. (Avian Pathology, 2001, 30:142-148) has been withdrawn in view of applicants' amendments to the claims.

New Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

In the reply dated April 25, 2008, applicants amended claim 1 to recite that "from one to seven amino acids have been deleted, added or substituted." There is no written support for this limitation. In the reply, applicants provide alignments of two gB sequences from the 632 strain and the SA2 strain along with the instant gB sequence. These sequences are described on page 5, lines 25-30, of the specification as GenBank accession numbers. The alignments show that these sequences differ by 2 amino acids (the 632 strain) and 7 amino acids (the SA2 strain) from the instant gB sequences. Therefore, there is written support for the 632 and SA2 gB sequences. There is no written support for other gB sequences containing 2 or 7 amino acid changes or for gB sequences containing 1 or 3-6 amino acid changes.

Maintained Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The claims are drawn to, *inter alia*, a recombinant herpesvirus that is not infectious laryngotracheitis virus, wherein the recombinant herpesvirus has a DNA that encodes the polypeptide of SEQ ID NO: 2, or encodes a modification of SEQ ID NO: 2 in which from one to seven amino acids have been deleted, added, or substituted, but that does not encode any other portion of the gB gene of infectious laryngotracheitis virus.

The written description rejection is made because the claims are interpreted as being drawn to a genus of recombinant viruses having a DNA that encodes a polypeptide (e.g., SEQ ID NO:2) in which one to seven amino acids have been deleted, added, or substituted in said polypeptide. The applicable standard for the written description requirement can be found in MPEP 2163; University of California v. Eli Lilly, 43 USPQ2d 1398 at 1407; PTO Written Description Guidelines; Enzo Biochem Inc. v.

Gen-Probe Inc., 63 USPQ2d 1609; Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111; and University of Rochester v. G.D. Searle & Co., 69 USPQ2d 1886 (CAFC 2004). To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claims is SEQ ID NO:2. There is no disclosure of any particular amino acids within the structure that must be conserved (or deleted, added, or substituted) to be a modification of SEQ ID NO:2.

The specification discloses at page 4 and 5 that "in accordance with the present invention, there is provided a recombinant herpesvirus (excluding infectious laryngotracheitis virus) having a DNA that encodes a polypeptide comprising 429 amino acids at the amino terminal end of a protein encoded by the gB gene of infectious laryngotracheitis virus or a polypeptide in which one or a plurality of amino acids have been deleted, added, or substituted in said polypeptide." (emphasis added) However, the specification does not indicate which amino acids of the 429 amino acid protein (i.e., SEQ ID NO:2) that are essential or which amino acids can be modified.

In the reply dated April 25, 2008, applicants amended claim 1 to recite that "from one to seven amino acids have been deleted, added or substituted." In the reply, applicants also provide alignments of two gB sequences from the 632 strain and the SA2 strain along with the instant gB sequence. These sequences are described on

page 5, lines 25-30, of the specification as GenBank accession numbers. These sequences differ by 2 amino acids (the 632 strain) and 7 amino acids (the SA2 strain) from the instant gB sequences. Therefore, there is a written description for the 632 and SA2 gB sequences. However, there is no guidance in the specification for making other amino acid substitutions, deletions, or additions within SEQ ID NO:2. One of ordinary skill in the art would not know where to make additional amino acid substitutions, deletions, or additions within SEQ ID NO:2.

Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

The court clearly states in *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111, that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not clearly allow persons of ordinary skill in the art to recognize that the inventors invented what is claimed. As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides with one to seven amino acids of SEQ ID NO:2 which can be deleted, added or substituted. Given that the specification has only described the structure of SEQ ID NO:2, the full breadth of the claims does not meet the written description provision of 35 U.S.C. 112, first paragraph.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicole E. Kinsey, Ph.D. whose telephone number is (571) 272-9943. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicole Kinsey White, PhD/
Examiner, Art Unit 1648

/Stacy B Chen/
Primary Examiner, Art Unit 1648

<div>Application Number</div> <div></div>	Application/Control No.	Applicant(s)/Patent under Reexamination	
	10/594,449	OKUDA ET AL.	
	Examiner	Art Unit	
	NICOLE KINSEY WHITE	1648	